

Mitchell E. Daniels, Jr. Governor

Gregory N. Larkin, M.D., F.A.A.F.P. State Health Commissioner

DATE:

July 30, 2010

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

A. Scott Gilliam, MBA, CP-FS

Director, Food Protection Program

SUBJECT:

Nutraloid Labs Inc.Recall

SUGGESTED

ACTION:

Unclassified Recall; two dietary supplement products sold under the names: Ejaculoid

XXTREME and Stimuloid II; Information provided in case of consumer inquiry.

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The recalled products listed below were distributed in black plastic bottles to distributors and via internet sales. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-

7360.

Recall -- Firm Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Nutraloid Labs Inc. Conducts Voluntary Nationwide Recall of Two Dietary Supplements Found to Contain Undeclared Drug Ingredient

Contact:

Bart Panessa 772-291-7510 **FOR IMMEDIATE RELEASE** -- Kingston, NY – July 28, 2010 – Nutraloid Labs Inc. announced today that it is conducting a voluntary nationwide recall of two dietary supplement products sold under the names: **ejaculoid XXTREME** and **stimuloid II**.

Nutraloid Labs Inc. has been informed by representatives of the Food and Drug Administration (FDA) that lab analysis of **ejaculoid XXTREME**, **Lot 79935**, and **stimuloid II**, **Lot 79936**, by the FDA found that the products contain sulfoaildenafil, similar in structure to Sildenafil. Sildenafil is an active ingredient of an FDA-approved drug for male Erectile Dysfunction (ED), making these products unapproved drugs. The active drug ingredient is not listed on the product label. The undeclared ingredient may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

The recalled products listed below were distributed in black plastic bottles to distributors and via internet sales.

Brand Name	Size	Lot	UPC
Ejaculoid XXTREME	30 Capsules/Bottle	79935 12/12	8 04879 17868 2
Stimuloid II	30 Capsules/Bottle		

No illnesses have been reported to the company to date in connection with these products.

Customers who have any of the above products in their possession should stop using them immediately and contact their physician if they have experienced any problems that may be related to taking these products.

Consumers and healthcare professionals should report any adverse events that may be related to the use of the above products to the FDA's Med Watch Adverse Event Reporting Program online at www.fda.gov/medwatch/report.htm⁹, by phone 1-800-FDA-1088, or by returning the postage-paid FDA form 3500 which may be downloaded from www.fda.gov/MedWatch/getforms.htm¹⁰ by mail to FDA Med Watch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax to 1-800-FDA-0178.

Nutraloid Labs Inc. is conducting this recall with the knowledge of the FDA. Consumers should return any unused product to the place of purchase or contact Nutraloid Labs Inc. directly at 1-772-291-7510, Monday – Friday, 10 am to 4 pm EDT.

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Photos: Product Labels 11